February 8, 2021

Vascular Solutions, Inc.
Matt Nienstedt
Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K112571
Trade/Device Name: XL Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEZ, KRA

Dear Matt Nienstedt:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated October 6, 2011. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2021.02.08 08:06:34 -05'00'

Gregory O'Connell
Assistant Director
Plaque Modification Devices Team
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Vascular Solutions, Inc
c/o Matt Nienstedt
6464 Sycamore Court
Minneapolis, MN 55369

OCT - 6 2011

Re: K112571
Trade/Device Name: XL Extraction Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II (two)
Product Code: DXE
Dated: September 2, 2011
Received: September 6, 2011

Dear Mr. Nienstedt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K112571

Device Name: XL extraction catheter

Indications for Use:

The XL extraction catheter is indicated for:

- the removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system
- the removal/aspiration of embolic material (thrombus/debris) from vessels of the deep venous system
- to infuse/deliver diagnostic or therapeutic agents

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112571

2 510(k) Summary

OCT - 6 2011

[As required by 21 CFR 807.92]

510(k) Number: K112571

Date Prepared: September 27, 2011

Submitter's Information / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
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Fax: 763.656.4253
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General Information

Trade Name	XL™ extraction catheter
Common / Usual Name	extraction catheter
Classification Name	21 CFR 870.5150, embolectomy catheter
Predicate Device	Pronto .035" extraction catheter (K070403 - Vascular Solutions, Inc.)

Device Description

The XL extraction catheter is an over-the-wire embolectomy catheter that has a working length of 120 cm (straight tip model 5090) or 122.5 cm (pigtail tip model 5091 when tip is straightened). The device is delivered over a 0.035 inch guidewire and through a 14F or larger introducer sheath. Proximal to the tip, the catheter has an extraction lumen opening supported by nitinol and has radiopaque marker bands on each side of the opening. The catheter lumen is constructed with a PTFE liner, stainless steel braid, and various durometers of Pebax® (polyether block amide) resin loaded with barium sulfate. This construction creates a radiopaque shaft transitioning from a stiff proximal region to a more-flexible distal region. A silicone oil wipe is applied to the distal end of the catheter as a lubricant to enhance deliverability.

The proximal end of the catheter has a strain relief and hemostatic Y-junction hub. One branch of the hub is for the guidewire and the other for the attached extension line with roller clamp. The proximal end of the extension line has a custom luer fitting designed to be compatible with the custom luer tip of the supplied 60 mL vacuum-locking syringes. The supplied filter baskets can be used to filter blood aspirated during the procedure for laboratory analysis of any thrombus.

Intended Use / Indications

The XL extraction catheter is indicated for:

- the removal/aspiration of embolic material (thrombus/debris) from vessels of the arterial system
- the removal/aspiration of embolic material (thrombus/debris) from vessels of the deep venous system
- to infuse/deliver diagnostic or therapeutic agents

Technological Characteristics

The XL extraction catheter and predicate Pronto .035" devices have the following characteristics in common:

- Catheter shaft consists of various durometers of Pebax resin reflowed together over a stainless steel braid
- Radiopaque marker bands
- Lubricious silicone wipe
- Extraction rate ≥1 mL/second
- Sterilized by ethylene oxide

The XL extraction catheter and predicate Pronto .035" devices differ in the following:

- Some shaft materials and construction
- Tip configuration
- Dimensional differences

Substantial Equivalence and Summary of Studies

XL extraction catheters are substantially equivalent to the predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The device design was qualified through the following verification/validation and biomaterial tests:

- Dimensional verifications
- Visual inspections
- Simulated anatomy/concomitant device use
- Thrombus aspiration
- Extraction rate
- Kink testing
- Torque testing
- Air aspiration
- Liquid leak and flush
- Tensile
- Radiopacity
- Biocompatibility
    - Cytotoxicity
    - Sensitization
    - Irritation/intracutaneous reactivity
    - Acute systemic toxicity
    - Material-mediated pyrogens
    - Hemocompatibility
        - Hemolysis
        - Coagulation
        - Prothrombin time
        - Hemotological parameters
        - Complement activation
        - Thrombogenicity

Results of non-clinical testing met the specified acceptance criteria, did not raise new questions of safety or effectiveness, and demonstrate that the XL extraction catheter is substantially equivalent to the predicate device.